REMARKS

This Amendment is being filed in response to the Office Action mailed on November 13, 2007.

On pages 2-4 of the Office Action the Examiner rejected claims 1-6 and 8-22 under 35 U.S.C. 102 (a,e) as being anticipated by U.S. 2001/0046964 (hereinafter "the '964 application).

Reconsideration is requested.

Claim 1 of the present application has been amended to more particularly point out the present invention. Specifically, the extruded dosage form has been designated as "once-a-day" and the requirement that "said extruded composition releases less than 50% of said total bupropion at 10 hours" has been added to claim 1. Further, the immediate release component recitation has been moved before the description of the release profile to improve the clarity of the overall claim. These amendments have been made to more specifically point out that the presently claimed invention comprises at least two separate components, an enteric coated component comprising bupropion and an immediate release component comprising bupropion. Additionally, the recitation of "at least one polymer for controlled release" has been added to claim 1. Support for these amendments can be found in the specification as originally filed, and specifically at paragraph 0028, and claim 4. No new matter has been added.

The '964 application teaches a controlled release dosage form that can release drug for approximately 6-12 hours. Examples 1-3 of the '964 application show release of drug up to approximately 7 hours, while Example 4 discloses release of drug for approximately 12 hours, with 83.5% released after 10 hours.

Moreover, the '964 patent is not specifically directed towards dosage forms containing bupropion. The only disclosure of bupropion in the '964 application is in two long lists of active ingredient. The first is in paragraph 0020 of the '964 application, and the second is in claim 6, wherein both instances recite sixteen active ingredients from which bupropion must be selected. The selection of the active ingredient from these lists and implementation into a possible dosage form as suggested by the specification of the '964 application would require excessive experimentation to produce a viable product. Moreover, as demonstrated by the dissolution data provided in the specification of the

'964 application, such a dosage form would not provide once-a-day therapy, but would only release active for approximately 6-12 hours. In contrast the present invention is a once-a-day product that releases active for 12-24 hours.

Applicants submit that each and every element of amended claim 1 of the present invention is not disclosed by the '964 application and therefore it is requested that the above 102(a, e) rejection be withdrawn.

On pages 4-5 of the Office Action the Examiner rejected claims 1-6 and 8-22 under 35 U.S.C. 103 (a) as being unpatentable over the '964 application.

Reconsideration is requested.

As discussed above, the '964 application does not disclose an extruded once-a-day bupropion dosage composition. Applicants submit that the '964 application also does not suggest an extruded once-a-day bupropion composition. The '964 application only teaches a dosage form that releases active for approximately 6-12 hours. While this method of treatment may be optimal for sotalol hydrochloride, it is not the release profile recited in the claims of the present application.

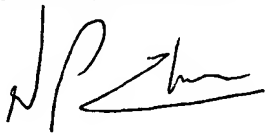
Further, Applicants submit that there is no in vivo release data anywhere in the specification of the '964 application for bupropion or even for sotalol. Therefore the '964 application cannot disclose or suggest the presently claimed release profile for bupropion. Also, as discussed above, the selection of bupropion from the long list of active ingredients recited in the '964 application would require undo experimentation.

The '964 application does not specifically teach a dosage for containing bupropion and it does not disclose or suggest a once-a-day product. Therefore, based on the above, it is requested that the 103(a) rejection be withdrawn.

Based upon the above amendment and remarks, Applicants respectfully submit that Claims 1-6 and 8-22 are allowable and that the present application is in proper form for allowance.

An early and favorable action is earnestly solicited.

Respectfully submitted,



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